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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,674	11/17/1999	MARK E. LEWIS	6622.US.01	4770

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EXAMINER

CROSS, LATOYA I

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/09/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/441,674

Applicant(s)

LEWIS ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-22, 24 and 26-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-22, 24 and 26-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on June 27, 2003 and entered as Paper No. 18. Claims 1, 4-22, 24 and 26-62 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 9, 10, 12-18, 21-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,580,794 to Allen (hereinafter Allen '794).

Applicants' invention is directed to a test strip for use in combination with a measuring device comprising a support, at least one reaction area, and an indicator.

Allen '794 teaches a disposable electronic assay device. The device comprises a test strip containing a sample receptor for receiving a sample to be tested, a sample treatment element for reaction with the sample to yield a detectable change, an electrical signal produced by a detector to correlate the amount of analyte in the sample, and a signal processor for outputting a visually readable result. See abstract. The test strip (10) has a pair of electrodes (12) mounted between the sample receptor zone (14) and the reagent zone (16). (col. 7, line 62 – col. 8, line 15). The reagents may be dry formulated on a matrix which can be a bibulous material such as porous plastic (col. 10, lines 33-43). The reagent zone may comprise reagents such as enzymes, antibodies, antigens, etc. (col. 16, lines 16-21). The detectable change is a change in reflectivity, transmission or electrical current (col. 7, lines 41-61). The signal

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processing means may include an analog to digital conversion means. Assays for glucose, cholesterol, triglycerides, etc. may be detected by the devices. In addition, single or multiple assays can be done at one time.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Allen '794.

3. Claims 1-8, 10-22, 24, 26 and 28-62 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,312,590 to Gunasingham (hereinafter Gunasingham '590).

Gunasingham '590 teaches a device for detecting chemical species in liquids. The test device comprises measuring electrodes (2) and reference electrodes (4) coated with a reaction layer (11) and a membrane layer (12). At least one of the electrodes is made by screen-printing carbon ink onto the base strip (1), as recited in claims 37, 48, and 59 (col. 6, lines 35-37). Each of the electrodes is made of gold, platinum, silver, graphite, etc, as recited in claims 36, 47, and 58. The measuring apparatus used in conjunction with the test device connects to the reference/working electrode pairs. The device is used in sensing blood glucose levels using the enzyme glucose oxidase, as recited in claims 30-34, 41-45 and 52-56. With respect to claims 38, 39, 49, 50, 60 and 61, Gunasingham teaches the electrode being on one part of the test strip surface and the indicator being on another part of the test strip. See figure 3. Since Applicants' are unspecific as to what they intend "major surface" to mean, the Examiner takes the position that each part of the test strip would constitute a major surface. With respect to claims 29 and 51, Gunasingham teaches multiple holes. While these holes may not be used for the same functions Applicants recite, functional differences from the prior art cannot be used to distinguish the claimed invention. See MPEP 2114.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102, in view of the teachings of Gunasingham '590.

Response to Arguments

4. Applicant's arguments filed June 27, 2003 have been fully considered but they are not persuasive. Applicants continue to argue that neither Allen nor Gunasingham teach that an indicator on the test strip allows the measuring device to choose one of a multiplicity of functionalities to be performed at a particular time. Applicants' arguments focus on the fact that in both Allen and Gunasingham, when multiple testing is performed, the testing is performed at the same time. Applicants point out that the idea of their invention involves selecting one of multiple testing functionalities and performing that test at a particular time. As stated in the previous Office Action, Applicants' claims do not provide for this limitation. In considering the most recent amendment, Applicants have not narrowed the claims to exclude multiple tests being performed at the same time, as taught by both Allen and Gunasingham. Both references teach that multiple tests may be performed. Both references also teach that a single test may be performed. There is nothing in Applicants' claims that excludes the tests being performed at the same time. Thus, the rejections are maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until

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after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC
September 7, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700